The Commonwealth of Massachusetts
Board of Registration in Pharmacy
Bureau of Health Professions Licensure
250 Washington Street, Boston, MA 02108-4619
Tel: 617-973-0960
Fax: 617-973-0980
TTY : 617-973-0988
Pharmacy.Admin@mass.gov

Relocation of a Facility

The following requirements shall apply to any Board of Registration in Pharmacy (Board) licensed or registered facility that is moving to a **new address**. Review 247 CMR for complete information regarding applicable relocation regulations. If additional information is necessary, please contact the Board office.

The facility **shall not begin to operate in the new location** until the application has been approved by the Board and the facility has received an updated license/registration and controlled substances registration, as applicable.

Fees: A check or money order for the relocation application fee and controlled substance registration (if applicable) must be payable to the ***Commonwealth of Massachusetts***.

Note: Do not send cash, foreign currency, or electronic funds transfers. There will be a $23 handling charge for returned checks. **Fees are non-refundable and non-transferable**.

To obtain guidance from the Drug Enforcement Administration (DEA) regarding the impact of a relocation on the licensure status of an existing DEA Registration, please contact them at the following address:

J.F.K. Federal Building
Drug Enforcement Administration
Room E400
15 New Sudbury Court
Boston, MA 02203-0131
(617) 557-2200

Retain copies of all documents for your records.
Do not submit checklist.

Checklist of Documents to be Submitted

DO NOT SUBMIT CHECKLIST

☐ A fully and properly completed and signed and notarized Relocation Application (*see pages 4-9*) and associated fee.

$525 for pharmacies, including nuclear pharmacies
$750 for outsourcing facilities
$900 for wholesale distributors

☐ **Resident Facilities Only**: Controlled Substance Registration (CSR) application and associated fee. (*see page 8*)

☐ **Non-Resident Facilities Only**: If licensed or registered by your home-state, attach a copy of your current home-state license or registration. If not, please provide a statement indicating as to why not.

☐ If shipping federally controlled drugs, attach a copy of the facility's current DEA Registration Certificate.

☐ If applicable, submit a completed Petition for a Waiver for each regulation and section the facility is requesting to be waived at the new location.

☐ A list of all state(s) where the facility is licensed or registered.

☐ Return all previously issued permits, licenses, and/or registrations after relocation.

Ownership:

☐ If the facility is owned by an individual(s), provide the name of owner(s), address(es), and Social Security Number(s).

☐ If the facility is owned by a partnership, provide the partnership name, address, and FEIN number.

☐ If the facility is owned by a corporation, provide the corporation's name, address, FEIN number, state in which company is incorporated, names of corporate officers and their positions and addresses and either a copy of the:

- Articles of Organization, signed, and sealed by the Secretary of State if incorporated in Massachusetts; **or**
- Foreign Corporation Certificate, signed, and sealed by the Secretary of State pursuant to M.G.L. c.181, § 4 if incorporated in another state.

Pharmacies (*in addition to Documents to be Submitted*)

☐ An official blueprint or certified architectural plans drawn to scale (*see page 10*).

☐ **Sterile Compounding Pharmacies (including Nuclear Pharmacies) Only:** Sterile Compounding Pharmacy Compliance form for DRAFT sterile compounding regulations 247 CMR 17.00 (*see page 11 - 12*).

☐ **Resident Nuclear Pharmacies Only:** A copy of the Radiation Control Program (RCP) license.

☐ Hours of operation (*see page 9*).

☐ Name, license number, and Social Security number of Manager of Record (MOR).

☐ On a separate sheet of paper briefly describe the business model including any additional services the pharmacy will provide (e.g., compliance packaging, compounding, delivery, immunization, veterinary, long-term care, etc.).

☐ **Resident Pharmacies:** If proposing to locate within any healthcare facility, documentation of approval from the facility's licensing body(s) must be attached.

☐ **Resident Pharmacies:** A statement indicating that the Manager of Record will be present during the relocation of the controlled substances and pharmacy records and that they are aware of their responsibilities in maintaining both security and confidentiality during such transfer.

☐ Documentation attesting that the alarm and all motion detectors/sensors have been tested and are in working order.

☐ Complete the applicable Inspection Template within 30 days. (**Do not submit**.)

Outsourcing Facilities (*in addition to Documents to be Submitted*)

☐ Proof of a valid, current FDA registration pursuant to section 503B of the Federal Food, Drug and Cosmetic Act.

☐ Proof of FDA Inspection within the last two years at the **new location**.

**Proof of inspection may include a copy of the FDA's Notice of Inspection or Form 483, or publication of the inspection date(s) on the FDA website listing 503B registered outsourcing facilities.*

☐ Provide a list of the types of entities that you ship to [e.g., patients, hospitals, licensed clinics/surgical centers, practitioners (MD, DMD, DVM, APRM, PA-C), etc.]

Wholesale Distributors (*in addition to Documents to be Submitted*)

☐ An official blueprint or certified architectural plans drawn to scale (*see page 10*).

☐ Hours of operation (*see page 9*).

☐ Provide a list of the types of entities that you ship to [e.g., retail pharmacies, hospitals, licensed clinics/surgical centers, intra-company sales only, practitioners (MD, DMD, DVM, APRM, PA-C), etc.]

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Relocation Application

TO BE COMPLETED BY BOARD

CHECK $_____DATE_____

CHECK NO. _____RECEIPT NO. _____APP NO. _____

Demographic Information

Legal Name of Facility _____

All trade or business names ("D.B.A." names) _____

License/Registration No. _____ RCP License No. (nuclear pharmacy only): _____

FEIN No. _____

Tel. No. _____ E-mail _____

NABP e-Profile number (if applicable) _____

CURRENT Street Address (physical address) _____

City/Town _____ State_____ Zip Code _____

NEW Street Address (physical address) _____

City/Town _____ State_____ Zip Code _____

If a Wholesale Distributor, specify type of operation:

- ☐ Full-Service Wholesaler
- ☐ Distribution Center for Pharmacy Corporation
- ☐ Other_____

Name, phone number, and email address of the <u>contact person</u> for questions regarding this application:

Name_____

Address_____City_____State_____Zip Code _____

Tel. No. _____ E-mail _____

Suitability

Has the applicant or any owner or corporate officer ever owned, operated, or held an interest in any facility licensed or registered in Massachusetts?

☐ Yes ☐ No *If yes, please provide the facility's legal name and license or registration number*.

For the applicant or any owners and corporate officers, provide a <u>list of any licenses/registrations/certifications</u> in the United States or any country or foreign jurisdiction and the state/jurisdiction from which the license/registration/certification was originally issued. <u>Include proof of standing from each state or jurisdiction.</u> The verification must indicate the status of the license and any relevant disciplinary information.

Has the applicant or any owner or corporate officer owned, operated, or held an interest in any licensed or registered facility that was the subject of proceedings which resulted in the discipline, suspension, denial, or revocation of the facility's registration or license?

☐ Yes ☐ No *If yes, provide a full explanation on a separate page.*

Has the applicant or any owner or corporate officer owned, operated, or held an interest in any licensed or registered facility entered into a settlement agreement in resolution of a complaint resulting in the imposition of discipline on the facility's registration or license?

☐ Yes ☐ No *If yes, provide a full explanation on a separate page.*

Has the applicant or any owner or corporate officer ever had:

1) any convictions related to the distribution of drugs (including samples);
2) any felony convictions;
3) any suspension(s) or revocation(s) or other sanction(s) by federal, state, or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution, or dispensing of any drugs, including controlled substances, radiopharmaceuticals, and radioactive materials?

☐ Yes ☐ No *If yes, provide a full explanation on a separate page and attach a certified copy of each action and or court setting forth circumstances of such action(s).*

Has the applicant or any owner or corporate officer ever been <u>denied licensure</u> by any federal or state agency including any state board of pharmacy?

☐ Yes ☐ No *If yes, provide a full explanation on a separate page.*

Is the applicant or any owner or corporate officer the subject of pending disciplinary actions by a licensing/certification board located in the United States or any country or foreign jurisdiction?
☐ Yes ☐ No *If yes, provide a full explanation on a separate page.*

Has the applicant or any owner or corporate officer ever voluntarily surrendered or resigned a professional license to a licensing/certification board in the United States or any country or foreign jurisdiction?
☐ Yes ☐ No *If yes, provide a full explanation on a separate page and attach a certified copy of each action and or court setting forth circumstances of such action(s).*

Affidavit (*must be signed and notarized)*

I certify under the penalties of perjury that I am the person authorized to sign this application and that all information provided is truthful, complete, and for lawful and honest purposes.

I, and my facility, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law pursuant to M.G.L. c. 62C, § 49A.

I have read and understand all applicable state and federal statutes and regulations regarding the operation of the facility and will notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).

Each employed person has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law or regulation.

WARNING: In accordance with Chapter 94 M.G.L. Sec 13, the Board of Registration in Pharmacy may suspend or revoke a license or registration to distribute, dispense, or possess a controlled substance after a hearing pursuant to the provisions of Chapter 34A and upon finding that the licensee/registrant has furnished false or fraudulent information in any application filed under the provisions of Chapter 94C.

_____ _____

Name of owner, corporate officer, MOR/PIC Title

_____ _____

Signature Date

Sworn and subscribed before me this _____ day of _____

Notary Public Signature _____My commission expires _____

NOTARY SEAL

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Controlled Substance Registration (CSR) Application
(MA Resident Facilities Only)

I hereby apply for a Controlled Substances Registration in accordance with M.G.L. c. 94C, § 7 with the associated **fee of $225**.

Name of Facility _____License No._____

Street Address _____

City/Town _____ State_____ Zip Code _____

Tel. No. _____ E-mail_____

FEIN Number: _____ RCP License No. (nuclear pharmacy only): _____

License / Registration Type:

☐ Pharmacy ☐ Outsourcing Facility ☐ Wholesale Distributor

Please check applicable controlled substance(s):

☐Schedule II ☐Schedule III ☐Schedule IV ☐Schedule V ☐Schedule VI**

**** Schedule VI: This substance is any prescription drug that has not already been included in Schedules II-V.**

Signature of Owner _____

Printed Name of Owner _____

TO BE COMPLETED BY BOARD

CHECK $_____DATE_____

CHECK NO. _____RECEIPT NO. _____APP NO. _____

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Hours of Operation

Name of Facility _____License No._____

Street Address _____

City/Town _____ State_____ Zip Code _____

Tel. No. _____ E-mail_____

Days	Open	Closed	Hours
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			
Total hours per week			

For pharmacies, please describe how a patient may contact a pharmacist for questions or refill their prescription when the pharmacy is closed.

_____

Signature of MOR, PIC, or Duly Authorized Representative

_____ **Date**_____

Printed Name

Requirements for Certified Blueprints/Architectural Drawings

Drug Store Pharmacy	A **blueprint/architectural drawing** with the pharmacy outlined in **RED**, drawn to scale with the following items clearly labeled: 1. square footage* 2. prescription area 3. a legend explaining all abbreviations 4. patient consultation area 5. drop off and pickup windows 6. pick-up bins 7. refrigerator 8. safe 9. sink 10. designated non-sterile compounding area (draft 247 CMR 18.00 will require 10 square feet of counter space for non-sterile compounding) 11. other pertinent details ***** DO NOT include areas such as consultation rooms, front store area, offices, or restrooms in the proposed licensed square footage total.
Complex Non-Sterile Compounding Pharmacy	A **certified blueprint**** with the pharmacy outlined in **RED**, drawn to scale with the following items clearly labeled: 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. the dedicated compounding room, including placement of containment hood(s) 4. detailed HVAC design plan and written description 5. hazardous drug storage area, if applicable 6. other pertinent details.
Sterile Compounding Pharmacy	A **certified blueprint**** with the pharmacy outlined in **RED**, drawn to scale with the following items clearly labeled: 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. proposed pharmacy layout outlined in red, include square footage of each room 4. location and ISO classification of each primary and secondary engineering control 5. air flow 6. room pressurization 7. detailed HVAC design plan and written description 8. location of any pass-throughs 9. hazardous drug storage area, if applicable 10. other pertinent details.

**** All blueprints/architectural drawings must be submitted electronically.**
A certified blueprint must be stamped with an architect's seal along with the architect's signature.

Sterile Compounding Pharmacy Compliance

If the proposed design meets the listed requirement, please indicate by placing "Y" (yes) or "N" (no) and include comments as to the reason for the non-compliance and plans to mitigate. If not applicable, indicate with "NA".

Please note that this is not an all-inclusive list of proposed standards in Draft 247 CMR 17.00 or the requirements of USP. At a minimum, applicants are required to adhere to the standards set forth in the most recent version of USP <797> and USP <800>. It is the responsibility of the applicant to be familiar with the requirements set forth in USP chapters and the Board's regulations.

Draft 247 CMR 17.00	Citation	Y/N	Comments
Miscellaneous:			
A pharmacy may not compound non-sterile preparations in any Primary Engineering Control (PEC) or Secondary Engineering Control (SEC) used for sterile compounding.	17.03(8)		
A pharmacy shall have a dedicated changing area for sterile compounding personnel.	17.04(2)		
Primary Engineering Controls (PECs):			
A pharmacy shall utilize only commercially manufactured PECs.	17.06(1)		
All Secondary Engineering Controls (SECs):			
The doors leading into and between ISO Classified SECs shall be constructed with an interlocking design or utilize an alternative method to ensure that doors are not opened simultaneously.	17.07(1)(c)		
Unless prohibited by local building or fire code, an SEC may not have more than one door to immediately adjacent areas.	17.07(1)(b)		
Each newly constructed SEC shall allow for visual observation through windows or technology.	17.07(1)(a)		
SECs may not contain windows to the outdoors.	17.07(1)(k)		
A pharmacy shall ensure that any pass-through chambers: a. have an interlocking door design; and b. are not refrigerator units.	17.04(1)		
Walls shall be made of solid surface materials such as locking sealed panels or epoxy-coated gypsum board.	17.07(1)(j)		
Ceiling panels, fixtures, and other penetrations through the ceiling or walls shall be smooth and sealed around the perimeter.	17.07(1)(h)		
SECs shall utilize light fixtures designed for sterile compounding areas (i.e., cleanroom grade) that have an exterior surface that is smooth, mounted flush with the ceiling, and sealed.	17.07(1)(g)		
Sprinkler heads shall be recessed, covered, and easily cleanable.	17.07(1)(i)		
Floors shall be composed of wide sheet vinyl that is heat sealed at the seams, or other solid, smooth surface, and coved at the wall or appropriately sealed.	17.07(1)(l)		
SECs may not contain floor drains.	17.07(1)(f)		
A pharmacy may not locate a refrigerator in any ISO Classified SEC.	17.07(1)(e)		

A pharmacy may not use ISO Classified areas for drug storage.	17.04(3)		
Ante Rooms:			
A newly constructed ante room shall be at least 72 square feet.	17.07(3)(a)		
For hand hygiene, an anteroom shall have a stainless-steel sink that is located on the clean side of the line of demarcation at least one meter away from the buffer room door.	17.07(3)(b)		
The stainless-steel sink shall: i. be equipped with hands-free controls for water and soap dispensing; ii. have proper depth and capacity for hand washing up to the elbows; iii. minimize splashing and dripping of water; iv. be designed to prevent standing water; and v. have a faucet that does not have an aerator mechanism on the nozzle.	17.07(3)(c)		
An ante room shall have low-lint, disposable towels located in close proximity to the sink.	17.07(3)(d)		
Buffer Rooms:			
A newly constructed **non-hazardous drug** buffer room shall be at least 100 square feet.	17.07(2)(a)		
A newly constructed **hazardous drug** buffer room shall be at least 72 square feet.	17.07(2)(b)		
Buffer room doors shall be hands-free.	17.07(2)(c)		
HVAC			
Newly constructed ISO Classified SECs shall utilize a closed loop ducted system, a sealed plenum system, or equivalent HVAC design.	17.05(1)		
Supply air provided for each ISO Classified SEC shall be provided exclusively through ceiling mounted HEPA filters.	17.05(3)		
Air returns in ISO Classified SECs shall be mounted low on the walls	17.05(4)		
If utilized, relief air vents shall be mounted low on the wall and designed to prevent the ingress of less clean air or contaminants from adjacent areas.	17.05(5)		
Temperature/Humidity			
A pharmacy shall have a system to continuously measure the temperature and humidity of each SEC. The quantitative results shall be reviewed and documented at least daily on all days the pharmacy is open.	17.10(3)		
SECs shall maintain a temperature of 68 degrees Fahrenheit (20 degrees Celsius) or lower.	17.10(1)		
SECs shall maintain relative humidity of 60% or lower.	17.10(2)		